

Attachment 3 – 510(k) Summary**510(k) Summary for Levitronix CentriMag Primary Console**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information:

Date Prepared: December 27, 2005

Submitter's Name & Address: Levitronix LLC
45 First Avenue
Waltham, MA 02451

Contact Person: Farzad Parsaie
V.P., RA/QA
Ph: (781) 622-5075
Fax: (781) 622-5090
e-mail: fparsaie@levitronix.com

B. Device Information:

Trade or Proprietary Name: Levitronix CentriMag® Primary Console

Common or Usual Name: Cardiopulmonary Bypass Pump
Console

Classification Name: Class II, DWA, 21 CFR – 870.4380
Control, Pump Speed, Cardiopulmonary
Bypass

Performance Standard: Performance standards do not currently
exist for these devices. None
established under section 514 of the
Food, Drug and Cosmetic Act.

C. Predicate Device:

Levitronix CentriMag Console (K020271)

D. Device Description

The CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data, system options, and menus. Operator adjustable alarms and parameters are accessible via the system menus.

E. Intended Use

The Levitronix CentriMag Primary Console is indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The Levitronix CentriMag Primary Console has technological characteristics similar to the predicate device.

The Levitronix CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data.

The CentriMag Primary Console uses single phase AC power and is capable of a flow rate of up to 9.9 LPM. Each Primary Console contains a rechargeable internal battery that is capable of maintaining Primary Console functionality in the event of a loss of AC Power.

G. Comparison to Predicate Device

The Levitronix CentriMag Primary Console has indications for use which is substantially equivalent to the predicate device, is composed of the same or equivalent materials as the predicate device, has equivalent design features as the predicate device, and has functional characteristics which are the same or equivalent to those of the predicate device. Due to the

equivalency of indications for use, materials of composition, design features, and functional characteristics, the device raises no new safety or effectiveness issues.

H. Summary of Performance Data

The performance characteristics of the Levitronix CentriMag Primary Console were tested and compared with Levitronix performance specifications established for the device and with the commercially available predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Levitronix LLC.
c/o Mr. Farzad Parsale
V.P., RA/QA
45 First Avenue
Waltham, MA 02451

Re: K053630

CentriMag® Primary Console (with v200 Application Software onboard)

Regulation Number: 21 CFR 870.4380

Regulation Name: Cardiopulmonary Bypass Pump Speed Control

Regulatory Class: Class II (Two)

Product Code: DWA

Dated: December 27, 2005

Received: January 4, 2006

Dear Mr. Parsale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

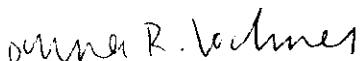
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1 – Indications for Use Statement

Applicant: **Levitronix LLC**

510(k) Number (if known): K 053630

Device Name: **CentriMag® Primary Console (with v2.00 Application Software onboard)**

Indications for Use:

The Levitronix CentriMag Primary Console is indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwaine R. Wickner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053630

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